CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

September 26, 2007

H.R. 3580
Food and Drug Administration Amendments Act of 2007

As cleared by the Congress on September 20, 2007

SUMMARY

H.R. 3580 would authorize the collection and spending of user fees by the Food and Drug Administration (FDA) for certain activities to expedite the marketing approval of prescription drugs and medical devices and to regulate prescription drugs after they enter the market. Such fees would be collected and made available for obligation only to the extent and in the amounts provided in advance in appropriation acts. In addition, the act would enhance FDA's authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials. H.R. 3580 also would alter the process for submitting petitions to FDA by the public regarding certain drug applications and it would modify procedures relating to that petition process. Discretionary costs of implementing the act relating to such activities are not discussed here; this cost estimate addresses only the effects H.R. 3580 would have on direct spending and revenues.

H.R. 3580 contains provisions that would both increase and decrease direct spending. Overall, CBO estimates that enacting H.R. 3580 would reduce direct spending, on net, by $80 million over the 2008-2012 period and by $4 million over the 2008-2017 period. We estimate that enacting H.R. 3580 would increase net federal revenues by $16 million over the next five years and by a negligible amount over 10 years through 2017.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated impact of H.R. 3580 on direct spending and revenues is shown in the following table. The effects of direct spending fall primarily within budget functions 550 (health) and 570 (Medicare).

	By Fiscal Year, in Millions of Dollars											
	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2008-2012	2008-2017
CHANGES IN DIRECT SPENDING												
Estimated Budget Authority	-3	-15	-21	-22	-19	-16	-9	6	33	62	-80	-4
Estimated Outlays	-3	-15	-21	-22	-19	-16	-9	6	33	62	-80	-4
CHANGES IN REVENUES												
Estimated Revenues												
On-budget	0	2	3	3	2	2	1	-1	-4	-8	10	*
Off-budget	0	1	1	2	2	*	*	*	-3	-4	6	*
Total Changes	0	3	4	5	4	2	1	-1	-7	-12	16	*

Note: * = between -$500,000 and +$500,000.

Direct Spending

H.R. 3580 contains provisions that would both increase and decrease direct spending associated with payments by federal health programs for pharmaceuticals. Those provisions would change when lower-priced generic drugs would be available on the market and would affect the average price of drugs paid by mandatory health programs, such as Medicare, Medicaid, the Federal Employees Health Benefits program, and the TRICARE for Life program. (Such changes would also affect federal revenues.)

H.R. 3580 would extend the authority for FDA to administer an incentive program that grants market exclusivity to manufacturers that voluntarily conduct studies on the use of such drugs in certain pediatric populations, the so-called "pediatric exclusivity program." The act would require that affected periods of existing market exclusivity be extended by an additional six months if the manufacturer meets specified requirements. (During such period of market exclusivity, FDA could not permit another manufacturer to market a version of the drug.) H.R. 3580 also would provide drug sponsors the opportunity to elect five-year data exclusivity for drugs developed from a particular type of molecule called an enantiomer under certain circumstances. (Five-year data exclusivity begins when the drug is approved by FDA; during such period, FDA will not accept an application for marketing approval of a generic version of the drug because FDA cannot use data submitted for approval of a brand drug to evaluate the generic drug's application.) CBO expects that granting data exclusivity

and extending market exclusivity for certain prescription drugs would delay the entry of lower-priced generic versions of those drugs in some cases. Because delaying the availability of lower-priced generic drugs would raise the cost of pharmaceuticals paid by mandatory health programs, CBO anticipates that direct spending for such programs would increase as a result.

H.R. 3580 also would accelerate the entry of lower-priced generic drugs by reducing the extent to which petitions submitted to FDA by the public regarding certain generic drug applications would delay their approval. (The act would modify the process for submitting petitions to FDA and it would alter procedures relating to FDA's review of such petitions.) Therefore, we estimate that such changes in the petition process would generate savings in direct spending by federal health programs each year through 2017. Starting in 2015, however, we expect that higher spending by mandatory health programs associated with granting pediatric and data exclusivities to certain drugs would exceed the annual savings generated by modifying the citizen petition process. Taken together, CBO estimates that enacting H.R. 3580 would reduce net direct spending by an estimated $80 million over the 2008-2012 period and $4 million over the 2008-2017 period.

Revenues

H.R. 3580 would affect revenues in two ways. First, it would make certain violations of new requirements under the bill subject to civil money penalties; collections of such penalties are classified as federal revenues**.** Second, changes in spending for prescription drugs that stem from the effect of several provisions of H.R. 3580 on the entry of lower-priced generics in the market would affect the cost of premiums for private health insurance**. (**See the earlier discussion on provisions affecting the market entry of generic drugs in the section on direct spending.)

The act would modify procedures relating to the citizen petition process at FDA. CBO expects that such changes, on balance, would accelerate the market entry of generic drugs and thereby reduce annual spending by employers on pharmaceutical health benefits through 2017. Other provisions relating to granting pediatric and data exclusivities to certain drugs would delay the market entry of some generic drugs and would increase the cost of private health insurance. Over the 2008-2012 period, lower premiums, on net, would result in less of an employee's compensation being received in the form of nontaxable employer-paid premiums, and more in the form of taxable wages. As a result of this shift, federal income and payroll tax revenues would increase. CBO estimates that H.R. 3580 would increase federal revenues by $16 million over the 2008-2012 period.

Beginning in 2015, CBO expects that annual health insurance premiums, on net, would increase as the costs associated with providing pediatric and data exclusivities exceed the savings generated by changes to the citizen petition process. As a result, revenues would be reduced starting in 2015. Overall, we estimate that enacting H.R. 3850 would have a negligible net effect on revenues over the 2008-2017 period. Social Security payroll taxes, which are off-budget, would account for $6 million of the $16 million revenue increase in the first five years; H.R. 3580 would have negligible net effect on such taxes over 10 years through 2017.

PREVIOUS CBO ESTIMATES

On April 27, 2007, CBO transmitted a cost estimate for S. 1082, the Prescription Drug User Fee Amendments of 2007, as reported by the Senate Committee on Health, Education, Labor, and Pensions on April 24, 2007. On July 2, 2007, CBO transmitted a cost estimate for H.R. 2900, the Food and Drug Administration Amendments of 2007, as approved by the House Committee on Energy and Commerce on June 21, 2007. The differences in the estimated costs reflect the differences in the three versions of the legislation.

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